SUMMARY OF SAFETY AND EFFECTIVENESS
Single Dose Dispensing Pin

SUBMITTER INFORMATION

A.	Company Name:	ALARIS Medical Systems, Inc.
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2772
C.	Company Phone: Company Fax:	(858) 458-7563 (858) 458-6223
D.	Contact Person:	Renée L. Fluet Principal Regulatory Affairs Specialist ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	September 14, 2001

DEVICE IDENTIFICATION

A.	Generic Device Name:	Set, Intravascular Administration
B.	Trade/Proprietary Name:	Single Dose Dispensing Pin
C.	Classification:	21 CFR 880.5440, Class II
D.	Product Code:	LHI, I.V. Fluid Transfer Set

DEVICE DESCRIPTION

The Single Dose Dispensing Pin (Dispensing Pin) is a stand-alone, single use, disposable syringe access device which permits access to a medication vial without the use of a needle. The Dispensing Pin is connected to a needleless syringe and is inserted into the rubber stopper of a medication vial. The healthcare provider uses the Dispensing Pin to inject or withdraw fluid from a vial.

SUBSTANTIAL EQUIVALENCE

The Single Dose Dispensing Pin as manufactured is of comparable type and is substantially equivalent to the following predicate devices:

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued
Single Dose Dispensing Pin

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Micro Pin, MP-1000	B. Braun of America, Inc.	K790472	03/26/1979
One Time Vial Access Spike	ICU Medical, Inc.	K934561	02/10/1994

INTENDED USE

The Single Dose Dispensing Pin is a stand-alone, single use, disposable access device which permits syringe access to a medication vial without the use of a needle. The device is intended for use by healthcare professionals in a wide variety of healthcare environments including hospitals, healthcare facilities, and pharmacies.

The Single Dose Dispensing Pin is indicated for use with standard medication vials and needleless syringes for withdrawal and/or injection of fluid.

TECHNOLOGICAL CHARACTERISTICS

The Single Dose Dispensing Pin has the same technological characteristics as the predicate devices; the B. Braun Micro Pin (K790472) and the ICU Medical One Time Vial Access Spike (K934561). The devices consist of similar components made of the same type of materials using the same method of manufacture. The associated applications and intended use of the devices are the same. Since there are no technological differences, there are no new questions of safety and effectiveness.

PERFORMANCE DATA

The performance data supplied in this submission indicate that the Single Dose Dispensing Pin meets all specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Ms. Renee L. Fluet
Principal Regulatory Affairs Specialist
Alaris Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2733

Re: K013087
Trade/Device Name: Single Dose Dispensing Pin, Model 2201
Regulation Number: 880.5440
Regulation Name: Set, Intravascular Administration (I.V.) Fluid Transfer Set
Regulatory Class: II
Product Code: LHI
Dated: September 12, 2001
Received: September 17, 2001

Dear Ms. Fluet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 3 2001

INDICATIONS FOR USE

510(k) Number: K013087 **(To Be Assigned By FDA)**

Device Trade Name: **Single Dose Dispensing Pin**

Indications For Use:

The Single Dose Dispensing Pin is a stand-alone, single use, disposable access device which permits syringe access to a medication vial without the use of a needle. The device is intended for use by healthcare professionals in a wide variety of healthcare environments including hospitals, healthcare facilities, and pharmacies.

The Single Dose Dispensing Pin is indicated for use with standard medication vials and needleless syringes for withdrawal and/or injection of fluid.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Valencia Ascente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013087